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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/904,179 | 07/11/2001 | Dan K. Ahlgren | 5510US | 1180 |

20350 7590 10/01/2002

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

[REDACTED] EXAMINER

RAMANA, ANURADHA

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

3751

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|------------------------|------------------|
| Application No. | AHLGREN, DAN K. |
| 09/904,179 | |
| Examiner Anu Ramana | Art Unit 3751 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
5) Claim(s) ____ is/are allowed.
6) Claim(s) 1-7,9-17 and 20-27 is/are rejected.
7) Claim(s) 8,18 and 19 is/are objected to.
8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) Interview Summary (PTO-413) Paper No(s) _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference elements not mentioned in the description: "ALPHA." A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference element in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 1 is objected to because of the following informalities.

Claim 1, recites "top position" in line 4 and "bottom position" in line 6. This should be "top portion" and "bottom portion" respectively. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 22 recite the limitation "the surgical cannulae." There is insufficient antecedent basis for this limitation in each of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-5, 9-11, 14, 17, 23-26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Kohrs.

In regard to claims 1-5, Kohrs discloses an intervertebral support system 10 having a center portion 3 with a top recess 24a and a bottom recess 24b, a top portion 40 with a bottom recess and a bottom portion 40 with a top recess (Figure 1, Figure 4, col. 2, lines 10-13, col. 3, lines 40-47 and col. 7, lines 10-24). Kohrs also discloses that device 10 can have a single or double taper with grooves (col. 4, lines 50-60 and col. 6, lines 1-13). Kohrs further discloses that a top surface 43 of top portion 42 is coplanar, same radial plane, as the top surface 4 of center portion 3 and a bottom surface 43 of bottom portion 42 is coplanar with the bottom surface 2 of center portion 3 (Figure 1).

In regard to claims 9-11, Kohrs show the top and bottom portions 40 as having recesses defined by tapered ends (Figure 1) designed to engage with the ramp portions in the center portion 3 (Figure 4).

The method steps of claims 17, 23, 24 and 25 are inherently performed during the normal operation of device 10 of Kohrs as applied to claims 1 and 9 (col. 10, lines 8-65).

In regard to claims 26 and 27, Kohrs discloses an intervertebral support system 10 with a center portion 3 having a bottom recess 21a and a bottom portion 40 with a top recess wherein the top and bottom recesses interlock together when the top portion is positioned on top of the bottom portion (Figure 1, Figure 4, col. 2, lines 10-13, col. 3, lines 40-47, and col. 6, lines 1-5 and lines 8-13). Kohrs further discloses that a top surface 43 of bottom portion 42 is coplanar, same radial plane, as the top surface 4 of the top portion 3 (Figure 1).

The method steps of claim 27 are inherently performed during the normal operation of device 10 of Kohrs as applied to claim 26.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kohrs.

Kohrs discloses an intervertebral support system 10 with center, top and bottom portions wherein the center portion has curved top and bottom surfaces, the top portion has a curved top surface and the bottom surface has curved bottom surface (Figure 1). See discussion for claim 1.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a center portion with flat top and bottom surfaces, a top portion with a flat top surface and a bottom portion with a flat bottom surface as a matter of design choice, since applicant has not disclosed that the flat surfaces solve any stated problem or are for any particular purpose and it appears that the invention would perform equally well with curved surfaces.

Regarding claim 7, Kohrs discloses grooves for anchoring implant 10 between opposing vertebrae (col. 4, lines 53-56 and Figure 1).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kohrs in view of Nicholson et al.

Kohrs does not disclose that the top, center and bottom portions of device 10 are made from bone allograft.

Nicholson et al. teach that bone allograft material can be used to fabricate implant devices to match the elastic properties of the patient's bone (col. 4, lines 9-13).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized bone allograft as taught by Nicholson et al. for the purpose of fabricating device 10 of Kohrs to match the elastic properties of the patient's bone.

Claim 12, 13, 16 , 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kohrs in view of Brantigan.

Regarding claims 12-13 and 20-22, Kohrs discloses a cannula 502 for inserting device 10. Kohrs is silent about the size of device 10 (col. 10, lines 9-65).

Brantigan teaches that implants can be sized from 7 to 15 mm depending on where the implant is used in a patient's body to match the height of a vertebral disc.

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have appropriately sized cannula 502 to receive implant 10 sized to match the height of a patient's vertebral disc as taught by Brantigan.

Regarding claim 16, Kohrs does not disclose that the top, center and bottom portions of device 10 are made from metal.

Brantigan teaches the use of traditional materials such as nickel, chromium, cobalt, stainless steel or titanium to make biologically acceptable implants (see abstract, col. 1, lines 64-68 and col. 2, lines 1-7).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have made the top, center and bottom portions of device 10 of Kohrs with biologically acceptable metal as taught by Brantigan suitable for the intended use of device 10.

The method steps 20-22 are rendered obvious by the above discussion. See discussion for claim 17.

Allowable Subject Matter

Claims 8, 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6258125: Figure 11 and col. 11, lines 53-56.

US 6454806: Figures 1 and 6.

Art Unit: 3751

US 5865848: Columns 1 and 2.

US 6371989: Columns 1, 2 and 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached on 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0975.

AR

September 27, 2002



STEVEN O. DOUGLAS
PRIMARY EXAMINER